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EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 09/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,773

Applicant(s)

LEONHARDT, STEFFEN

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 6 is acknowledged.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

3. Claim 4 is objected to because of the following informalities. In claim 4, "it" in line 4 and line 5 should be "the piston". Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites the limitation "a catheter, the free end of which is positioned in a blood vessel" which improperly includes a body part as part of the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 9-10, 16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the limitation "the control line" in line 3 in which there is insufficient antecedent basis. Claim 9 recites the limitation "the control action" in lines 1-2 in which there is insufficient antecedent basis. Claim 10 recites the limitations "the control line" in lines 1-2 and "the piston" in line 3 in which there are insufficient antecedent bases. Claim 16 recites the limitation "the implant" in line 3 in which there is insufficient antecedent basis. Claim 20 recites the limitation "the measured values" in line 3 in which there is insufficient antecedent basis.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3, 9, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,623,248 to Sperinde in view of Japanese Patent Application Publication 08-029699 to Kitagawa. Sperinde teaches an apparatus that includes a catheter 24, a light source 4, a measurement point 30 inside a blood vessel, a detector 32, and a computer unit 74. (Fig. 4 of Sperinde). Sperinde does not teach the use of a cleansing device for removing tissue particles deposited from the blood. Kitagawa teaches that apparatuses that are inserted into a body fluid have the potential of debris adhering to the apparatus. (paragraph 0005 of Kitagawa). Kitagawa teaches a cleansing device that includes an actuator in the form of a wiper 6a for removing debris that would interfere with optical measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cleansing apparatus of Kitagawa in the device of Sperinde since debris from inside a body fluid may adhere to the measurement apparatus, which causes interference with optical measurements. In regard to claim 1, it is noted that the limitation "for measuring human blood sugar level" is merely "intended use" language, which cannot be relied upon to define over the combination since the combination discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. In regard to claim 3, a motor runs the wiper 6a. (paragraph 0016 of Kitagawa). In regard to claim 9, a switch connected to the motor activates the wiper, which is considered

means of an electrical control line. In regard to claim 12, the energy for controlling the wiper is supplied by mechanical means since the wiper is connected to a motor, which is connected to a switch. In regard to claim 13, reflection measurements are disclosed. (column 1, lines 55-64 of Sperinde).

10. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,623,248 to Sperinde in view of Japanese Patent Application Publication 08-029699 to Kitagawa as applied to claim 1, and further in view of U.S. Patent 5,333,609 to Bedingham et al. The combination does not teach the use of a biocompatible material. The combination teaches the use of a catheter but does not teach what material to use for the catheter. It is well known in the art to clad the catheter with a biocompatible material. (column 5, lines 66-68 of Bedingham et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biocompatible material since material selection is required and Bedingham et al. teaches one such material.

11. Claims 1 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,763,655 to Wirtzfeld et al. in view of U.S. Patent 4,623,248 to Sperinde, and further in view of Japanese Patent Application Publication 08-029699 to Kitagawa. Wirtzfeld teaches a frequency-controlled heart pacemaker, which includes an implanted pacemaker housing and a blood oxygen sensor. (Fig. 1 of Wirtzfeld et al.). Wirtzfeld et al. disclosed schematically a blood oxygen sensor that includes a light source 12, a

detector 13, and a processor 10. (Fig. 1 of Wirtzfeld et al.). Wirtzfeld et al. does not teach a specific physical embodiment of the blood oxygen sensor. Sperinde teaches an apparatus that includes a catheter 24, a light source 4, a measurement point 30 inside a blood vessel, a detector 32, and a computer unit 74. (Fig. 4 of Sperinde). The use of a catheter would fulfill the requirements of providing a physical embodiment of a blood oxygen sensor as set forth in Wirtzfeld et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the catheter for the blood oxygen sensor as disclosed by Sperinde since Wirtzfeld et al. requires a physical embodiment of a blood oxygen sensor and Sperinde teaches one such physical embodiment. The combination does not teach the use of a cleansing device for removing tissue particles deposited from the blood. Kitagawa teaches that apparatuses that are inserted into a body fluid have the potential of debris adhering to the apparatus. (paragraph 0005 of Kitagawa). Kitagawa teaches a cleansing device that includes an actuator in the form of a wiper 6a for removing debris that would interfere with optical measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cleansing apparatus of Kitagawa in the combination since debris from inside a body fluid may adhere to the measurement apparatus, which causes interference with optical measurements. In regard to claim 1, it is noted that the limitation "for measuring human blood sugar level" is merely "intended use" language, which cannot be relied upon to define over the combination since the combination discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. In regard to

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claim 16, the combination teaches processing unit with a power supply in the implant. (Fig. 3 of Wirtzfeld et al.). The combination also teaches that the light source and detector are also located in the housing with the processing unit. (Fig. 4 of Sperinde).

12. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,763,655 to Wirtzfeld et al. in view of U.S. Patent 4,623,248 to Sperinde, and further in view of Japanese Patent Application Publication 08-029699 to Kitagawa as applied to claim 16, and further in view of U.S. Patent 5,404,877 to Nolan et al. The combination does not teach the use of a telemetry unit. Nolan et al. teaches that it is well known in the art to use telemetric units in pacemakers so that physicians can program the pacemaker. (column 22, lines 16-23 of Nolan et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a telemetric device as disclosed by Nolan et al. so that physicians can program the pacemaker. In regard to claim 18, Nolan teaches that induction coils are used as antennas to transmit the data. (Fig. 1 of Nolan et al.). In regard to claim 19, capacitors are charged in telemetric device 68 when the device received energy in the form of data transmission. (Fig. 1 of Nolan et al.).

Allowable Subject Matter

13. Claims 2, 4-6 and 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. Claims 7, 10, and 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest that the cleansing device is controllable by the computer unit. The prior art does not teach or suggest the actuator comprising a piston which is inserted into a form-fitting opening located at the free end of the catheter and which moves between a position where it forms a seal flush with the catheter surface and a position where it fits into a recess located opposite the catheter surface, and that in the recessed position a light emission orifice of the at least one optical waveguide becomes free. The prior art does not teach or suggest that the control line consists of a hydraulic or pneumatic line, which is effectively connected to the piston, whereby a linear actuator is integrated to exert a force on the control line. The prior art does not teach or suggest a control unit located extracorporeally for regulating human blood sugar levels, wherein the measured values are transmitted by a telemetry unit to said control unit, an extracorporeal insulin pump for injecting insulin through the peritoneum, and a regulator integrated into the control unit which controls the insulin pump subject to the measured values in such a way that the desired blood sugar level is attained.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
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